



Our STN: BL 125613/0

PROPRIETARY NAME ACCEPTABLE

November 14, 2016

Kamada Ltd.
Attention: Ms. Holli S. Vaughan
Biologics Consulting Group, Inc.
400 North Washington Street, Suite 100
Alexandria, VA 22314

Dear Ms. Vaughan:

We have reviewed your August 29, 2016 submission to your Biologics License Application (BLA) for Rabies Immune Globulin (Human) requesting a proprietary name review for KEDRAB.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, KEDRAB is Acceptable.

Please note this product was transferred from the Office of Blood Research and Review (OBRR) to the Office of Tissues and Advanced Therapies (OTAT) effective October 16, 2016. For additional information see <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm525907.htm>.

If you have any questions, please contact the Regulatory Project Manager, Jiahua Qian, Ph.D., at (240) 402-8432.

Sincerely yours,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research